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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,094	10/21/2005	Katsuyoshi Nagao	06854.0046	6586

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EXAMINER	
MARCETICH, ADAM M	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,094	NAGAO ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-7,11-13 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-7, 11-13 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 October 2008* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03 September 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. PCT/JP/2004/005547, filed on 19 April 2004 has been received.

Drawings

2. The drawings filed 21 October 2008 are objected to because they consist of photographs, which contain darkened or blurred regions. Ordinarily, black-and-white schematic or diagram drawings are required. see MPEP 608.01(f), Brief Description of Drawings and 37 CFR 1.84. Standards for drawings.

3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1, 3-7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meierhoefer (US 4502616) in view of Peiffer; Herbert et al. (US 6068936).

7. Regarding claims 1, 4-7 and 12, Meierhoefer discloses an ampoule comprising:

[1] a flexible container body (column 3, lines 56-65 and Fig. 3, vials or ampoules 12);

[1] a fusion-bonded portion which seals a mouth of the container body (column 4, lines 25-36 and Fig. 3, seal 44); and

[1] a holder tab connected to the fusion-bonded portion for wrenching off the fusion-bonded portion (column 4, lines 25-36 and Fig. 3, key 26).

[1] The ampoule of Meierhoefer comprises plastic (column 3, lines 56-65), therefore it naturally follows that it is capable of preventing drug permeation.

[1] Meierhoefer discloses the invention substantially as claimed, see above. However, Meierhoefer lacks three or more layers as claimed [claim 1]. Peiffer discloses a multi-layered polyolefin film (col. 2, lines 49-62, col. 3, lines 7-19 especially lines 15-19), comprising three or more layers including:

[1] innermost and outermost layers composed of a polyolefin (col. 11, lines 12-60, especially lines 41, 42; example 1, layers B; 98.77% random ethylene-propylene copolymer; it is the Examiner's position that the remaining components do not materially affect the basic and novel characteristic of the claimed invention. See MPEP 2111.03, Transitional Phrases.

[1, 7] an intermediate layer composed of blends of a polyolefin and a polycycloolefin (col. 6, lines 33-39; col. 11, lines 12-60 especially lines 30-35; example 1, layer A; 94.85% by weight of isotactic polypropylene and 5.0% by weight of norbornene homopolymer);

[1, 12] wherein at least one of the layers is a functional layer having a gas permeation preventing capability (col. 11, lines 5-17, especially lines 13-17; water vapor and oxygen barrier properties of example 1, layer A).

[12] wherein the ampoule has a volume of 0.5 to 20mL (column 4, lines 7-9, volume of 5.0mL overlapping claimed range of 0.5 to 20mL).

[4] wherein the functional layer comprises a polyamide layer (col. 8, lines 35-45, col. 9, lines 13-25, especially line 17, antiblocking agent optionally added to inner layer, including polyamides);

[5, 6] wherein the functional layer comprises a polyol or polyester layer (col. 9, lines 13-25, especially line 18, polyesters, it naturally follows that polyester is a polyol);

[1] Regarding the functional layer, Peiffer provides the advantage of improved water vapor and oxygen barrier properties (col. 11, lines 5-17, especially lines 13-17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Meierhoefer as discussed with the three layers as taught by Peiffer in order to provide improve barrier properties.

[1, 3-12] Regarding the limitation of a "...container body [that] is molded by holding [a] parison," Examiner notes that claims 1 and 3-12 are drawn to a device, not a method of manufacture.

This rejection is made in light of ***In re Thorpe***, 227 USPQ 964 (CAFC 1985) wherein product-by-process claims to a drug solution filling plastic ampoule are rejected over vials or ampoules 12 of Meierhoefer, which although may be prepared in a different manner, appears to be the same (prima facie) as the claimed product and performs the same function as the claimed product does.

Because of the nature of product-by process claims, the Examiner cannot ordinarily focus on the precise difference between the claimed process of molding and

the disclosed vials / ampoules. It is then Applicants' burden to prove that an unobvious difference exists. See ***In re Marosi***, 218 USPQ 289, 292-293 (CAFC 1983).

In the instant case no Graham vs. John Deere analysis was made but rather the test set out in MPEP 706.03(e) and In re Marosi was applied while explaining why the claimed product does not patentably distinguish over the prior art under 35 USC 102/103.

Meierhoefer teaches that the vials or ampoules 12 comprise a polymer (col. 3, lines 56-65), but is silent as to the method of manufacture, namely being "integrally molded" and "molded by holding the parison between split mold pieces." The claimed phrase "container body . . . molded by holding" is being treated as a product by process limitation; that is, a container that is made by molding. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Meierhoefer is silent as to the process used to form the vials or ampoules 12, it appears that the product as taught by Meierhoefer would be the same or similar as that claimed; especially since both applicant's product and the prior art product comprise a polymer and are mass-produced.

8. Regarding claim 3, Meierhoefer discloses the invention substantially as claimed, see above. However, Meierhoefer lacks an additive as claimed [claim 3]. Peiffer discloses:

a layer provided as other than an innermost layer and composed of a material containing at least one additive selected from the group consisting of a colorant (col. 10, lines 51-59, col. 13, lines 33-39; corona-treated films printed with ink; it is the Examiner's position that printing places an additive on an outer layer, therefore an additive is provided on a layer other than the innermost layer); and

a layer provided inward of the additive-containing layer and having a drug permeation preventing capability (layer A as discussed for claim 1 above capable of preventing drug permeation). Peiffer provides the advantage of printing indicia directly on containers, which is valuable for labeling the contents of medical containers. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Meierhoefer as discussed with the colorant additive as taught by Peiffer in order to label medical containers.

9. Regarding claim 11, Meierhoefer discloses an ampoule sequence including a plurality of ampoules connected to one another via severable thin wall portions (column 4, lines 45-49 and Fig. 1, separation strip 36).

10. Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Louviere (US 6254376) in view of Peiffer; Herbert et al. (US 6068936).

11. Regarding claim 13, Louviere discloses a production method for a drug solution filling plastic ampoule comprising the steps of:

molding a container body by holding a tubular parison between lower split mold pieces (column 5, lines 57-62 and Fig. 1, core pins 68, 70 and slide inserts 26, 28;

column 9, lines 47-65). Louviere discloses forming a hollow plastic article (column 9, lines 31-34) therefore it naturally follows that that Louviere has a step of forming a void in a parison.

A parison is defined as a partially shaped mass of molten glass (online dictionary, "parison"). Applicant has not further defined the term "parison" in the specification, therefore it is given its plain meaning. Liquidized plastic reasonably meets the definition of "parison" in the context of plastic molding.

Louviere discloses a step of filling a drug solution in a container body (column 10, lines 28-37).

Louviere substantially discloses holding a mouth of a container body between upper split mold pieces to form a fusion-bonded portion which seals the mouth of the container body and a holder tab which is connected to the fusion-bonded portion to be used for wrenching off the fusion-bonded portion (column 9, lines 34-41 and Fig. 8, rectangular extension top 240A and nearby neck).

Louviere discloses the invention substantially as claimed. However, Louviere lacks a parison having three or more layers as claimed [claim 13]. Peiffer discloses a multi-layered polyolefin film (col. 2, lines 49-62, col. 3, lines 7-19 especially lines 15-19), comprising three or more layers including:

innermost and outermost layers composed of a polyolefin (col. 11, lines 12-60, especially lines 41, 42; example 1, layers B; 98.77% random ethylene-propylene copolymer; it is the Examiner's position that the remaining components do not materially

affect the basic and novel characteristic of the claimed invention. See MPEP 2111.03, Transitional Phrases.

an intermediate layer composed of blends of a polyolefin and a polycycloolefin (col. 6, lines 33-39; col. 11, lines 12-60 especially lines 30-35; example 1, layer A; 94.85% by weight of isotactic polypropylene and 5.0% by weight of norbornene homopolymer);

wherein at least one of the layers is a functional layer having a gas permeation preventing capability (col. 11, lines 5-17, especially lines 13-17; water vapor and oxygen barrier properties of example 1, layer A).

Regarding rationale and motivation, see discussion of claim 1 above.

12. Regarding claim 15, Louviere discloses the invention substantially as claimed, see above. However, Louviere lacks an additive as claimed [claim 15]. Peiffer discloses:

a layer provided as other than an innermost layer and composed of a material containing at least one additive selected from the group consisting of a colorant (col. 10, lines 51-59, col. 13, lines 33-39; corona-treated films printed with ink; it is the Examiner's position that printing places an additive on an outer layer, therefore an additive is provided on a layer other than the innermost layer); and

a layer provided inward of the additive-containing layer and having a drug permeation preventing capability (layer A as discussed for claim 1 above capable of preventing drug permeation). Regarding rationale and motivation, see discussion of claim 3 above.

Response to Arguments

13. Applicant's arguments, see p. 6-9 filed 21 October 2008 with respect to the rejection(s) of claim(s) 1, 3-7, 11, 12 and 13 under 35 USC § 103 over Meierhoefer, Takanashi, Itoh, Komatsu and Louviere have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Meierhoefer, Pfeiffer and Louviere.

14. Applicant asserts that none of Meierhoefer, Takanashi or Itoh teach the composition of the claimed intermediate layer, namely one composed of blends of a polyolefin and a polycycloolefin. Examiner notes that Pfeiffer teaches an intermediate layer composed of blends of a polyolefin and a polycycloolefin in the new grounds of rejection.

15. Applicant contends that Louviere and Takanashi both lack the claimed intermediate layer. Examiner notes that Pfeiffer teaches the claimed intermediate layer for new grounds of rejection of claims 13 and 15.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Hirose; Toshiyuki et al. US 6165573
- Roberts; William P. et al. US 6872462
- Roberts, William P. et al. US 20040142195
- Childress; Blaine US 6479138
- Arthurs; Trevor et al. US 7179521
- Satani, Shoichi et al. US 20020192412

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is (571)272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
21 January 2009